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Clarifier A. Corbin

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2005D–0434]

Draft Guidance for Industry and Food and Drug Administration; Nucleic Acid Based In Vitro Diagnostic Devices for Detection of Microbial Pathogens; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the draft guidance entitled "Nucleic Acid Based In Vitro Diagnostic Devices for Detection of Microbial Pathogens." This draft guidance document is being issued to provide guidance on the types of information and data to consider when preparing or reviewing premarket submissions for nucleic acid based in vitro diagnostic devices for the detection of microbial pathogens.

DATES: Submit written or electronic comments on this draft guidance by [*insert date 90 days after date of publication in the* **Federal Register**].

ADDRESSES: Submit written requests for single copies on a 3.5" diskette of the guidance document entitled "Nucleic Acid Based In Vitro Diagnostic Devices for Detection of Microbial Pathogens" to the Division of Small Manufacturers, International, and Consumer Assistance (HFZ–220), Center for Devices and Radiological Health, Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850. Send one self-addressed adhesive label to assist that office in processing your request, or FAX your request to 301–443–8818. See

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the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance.

Submit written comments concerning this guidance to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to *http://www.fda.gov/dockets/ecomments*. Identify comments with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Roxanne Shively, Center for Devices and Radiological Health (HFZ–440), Food and Drug Administration, 2098 Gaither Rd., Rockville, MD 20850, 240–276–0496 ext. 113.

SUPPLEMENTARY INFORMATION:

I. Background

This draft document is intended to provide a basic framework for the types of information and data that we believe should be addressed in the premarket review of a nucleic acid based device for detecting microbial pathogens. This draft guidance replaces a previously issued document entitled "Review Criteria for Nucleic Acid Amplification-based in vitro Diagnostic Devices for Direct Detection of Infectious Microorganisms" (June 1993). The current draft reflects changes in the technologies available for nucleic acid detection, and expanded use in clinical laboratories. The recommendations within this draft guidance apply broadly to premarket review of these in vitro diagnostic devices for detecting microbial pathogens. Enzymatic amplification may or may not be part of the applied technology.

II. Significance of Guidance

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will

represent the agency's current thinking on "Nucleic Acid Based In Vitro Diagnostic Devices for Detection of Microbial Pathogens." It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute and regulations.

III. Electronic Access

To receive "Nucleic Acid Based In Vitro Diagnostic Devices for Detection of Microbial Pathogens" by FAX, call the CDRH Facts-On-Demand system at 800–899–0381 or 301–827–0111 from a touch-tone telephone. Press 1 to enter the system. At the second voice prompt, press 1 to order a document. Enter the document number (1560) followed by the pound sign (#). Follow the remaining voice prompts to complete your request.

Persons interested in obtaining a copy of the draft guidance may also do so by using the Internet. The Center for Devices and Radiological Health (CDRH) maintains an entry on the Internet for easy access to information including text, graphics, and files that may be downloaded to a personal computer with Internet access. Updated on a regular basis, the CDRH home page includes device safety alerts, **Federal Register** reprints, information on premarket submissions (including lists of approved applications and manufacturers' addresses), small manufacturer's assistance, information on video conferencing and electronic submissions, Mammography Matters, and other device-oriented information. The CDRH Web site may be accessed at *http://www.fda.gov/cdrh*. A search capability for all CDRH guidance documents is available at *http://www.fda.gov/cdrh/guidance.html*. Guidance documents are also available on the Division of Dockets Management Internet site at *http://www.fda.gov/ohrms/dockets*.

IV. Paperwork Reduction Act of 1995

This draft guidance contains information collection provisions that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (the PRA) (44 USC 3501–3520). The collections of information addressed in the draft guidance document have been approved by OMB in accordance with the PRA under the regulations governing premarket notification submissions (21 CFR part 807, subpart E, OMB control number 0910–0120 and premarket approval applications 21 CFR part 814, OMB control number 0910–0231). The labeling provisions addressed in the guidance have been approved by OMB under OMB control number 0910–0485.

V. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**), written or electronic comments regarding this document. Submit one copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in brackets in the heading of this

document. Comments received may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Dated: 11/28/05

November 28, 2005.

Linda S. Kahan

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[FR Doc. 05–????? Filed ??–??–05; 8:45 am]

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